

K091257

PG. 1 OF 2

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

### A. Submitter Information:

Date Prepared: March 9, 2009

MAY - 8 2009

Submitter's Name: Medi-Globe Corporation

Submitter's Address: 110 West Orion Street #136  
Tempe, Arizona 85283

Contact Person: Scott Karler

Contact Person's Telephone Number: (480) 897-2772 ext. 208

Contact Person's FAX Number: (480) 897-2878

Contact Person's Email Address: skarler@mediglobe.com

### B. Device Name:

Medi-Globe SonoTip II EBUS-TBNA Needle System

### C. Predicate Devices:

Medi-Globe SonoTip II Ultrasound Needle System (K070129)

Medi-Globe SonoTip II Ultrasound Needle System (K051247)

Olympus Medical Single Use Aspiration Needle NA-201SX-4022, (K050503)

### D. Device Description:

The Medi-Globe SonoTip II EBUS-TBNA Needle System is a complete one-piece needle system for Fine Needle Aspiration and is a disposable instrument intended for single patient use only.

### A. Intended Use:

The SonoTip II EBUS-TBNA Needle System is used in conjunction with various legally marketed, FDA registered Ultrasound Endoscopes. The SonoTip II EBUS-TBNA Needle System is used for ultrasonically guided fine needle aspiration, (FNA) of submucosal and extra-luminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract.

### F. Technological Characteristics Summary:

The Medi-Globe SonoTip II EBUS-TBNA Needle System utilizes endoscopic ultrasound technology which, when used with an ultrasound endoscope, allows the user to ultrasonically guide the biopsy needle to its intended target within or adjacent to the Tracheobronchial Tree or Gastrointestinal Tract.

G. Performance Data:

Design verification data has demonstrated that the proposed Medi-Globe SonoTip II EBUS-TBNA Needle System meets the same performance requirements and is as safe and effective as Medi-Globe's currently cleared predicate device. The SonoTip II EBUS-TBNA Needle System is considered to have the same intended diagnostic/therapeutic effect, method of introduction/use, technical characteristics and general range of descriptive features as the predicate Medi-Globe SonoTip II Ultrasound Needle System (K070129).



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

MAY - 8 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medi-Globe Corporation  
% Mr. Jay Y. Kogoma  
Responsible Third Party Official  
Intertek Testing Services NA, Inc.  
2307 E. Aurora Road, Unit B7  
TWINSBURG OH 44087

Re: K091257

Trade/Device Name: SonoTip II EBUS-TBNA Needle System

Regulation Number: 21 CFR 876.1075

Regulation Name: Gastroenterology-urology biopsy instrument

Regulatory Class: II

Product Code: FCG

Dated: April 28, 2009

Received: April 29, 2009

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

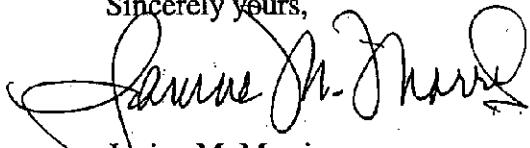
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

|                |                                  |                |
|----------------|----------------------------------|----------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology)          | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology)                      | (240) 276-0120 |
| Other          |                                  | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): TBD K091257

Device Name: SonoTip II EBUS-TBNA Needle System

Indications for Use: The SonoTip II Endobronchial Ultrasound-Guided Transbronchial Fine Needle Aspiration, (EBUS-TBNA) Needle System is used in conjunction with various legally marketed, FDA registered Ultrasound Endoscopes. The SonoTip II EBUS-TBNA Needle System is used for ultrasonically guided fine needle aspiration, (FNA) of submucosal and extra-luminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract.

Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin A. Pollard  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K091257